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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/631,953

07/31/2003

Bozidar Ferek-Petric

P8856.04

1782

27581 7590 08/06/2009
MEDTRONIC, INC.
710 MEDTRONIC PARKWAY NE
MINNEAPOLIS, MN 55432-9924

EXAMINER

RAJAN, KAI

ART UNIT

PAPER NUMBER

3769

MAIL DATE

DELIVERY MODE

08/06/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/631,953	Applicant(s) FEREK-PETRIC ET AL.	
	Examiner Kai Rajan	Art Unit 3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 7-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges the reply filed March 24, 2009.

Note to Applicant Regarding Claim Interpretation

The terms “for,” “adapted to,” and “wherein” in the claim(s) may be interpreted as intended use. Intended use/functional language does not require that reference specifically teach the intended use of the element. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Steil et al. U.S. PGPub No. 2003/0130616.

1. An interactive remote drug dose and physiologic response monitoring system in a patient under a prescriptive regimen to take a drug comprising:

- a drug delivery device (Paragraphs 0005, 0006, 0098, 0317); and
- an IMD in wireless communication with the drug delivery device (Paragraphs 0098, 0317), the IMD having means for monitoring the administration of a drug by the drug delivery device in compliance with a prescriptive regimen (Paragraphs 0005, 0006),

wherein the IMD monitors the patient's physiological signs subsequent to the administration of the drug, and checks drug interaction in the patient (Paragraphs 0005, 0006).

2. The system of claim 1, wherein the delivery device is chosen from one of the following: a pill box, a transdermal patch, a IV, an inhaler, an oral medicament dispenser, a subcutaneous implant, a drug pump, or a transcutaneous application (Paragraphs 0005, 0006).

6. An implantable medical device comprising:

- a microprocessor for controlling cardiac therapy parameters (Paragraphs 0005, 0006, 0098, 0317);
- a lead for delivering electrical stimulation to cardiac tissue and monitoring physiologic parameters of the tissue (Paragraph 0293); and
- a telemetry unit for receiving the parameters from the lead and information from a drug delivery device, the information identifying whether an expected drug therapy is delivered,

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wherein the microprocessor varies the cardiac therapy delivery through the lead based upon the information (Paragraphs 0005, 0006, 0098, 0293, 0317).

Claims 3 – 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Ellinwood, Jr. U.S. Patent No. 4,146,029.

3. A drug delivery monitoring system comprising:

means for monitoring parameters of a drug delivery device (Figure 28, column 3 lines 9 – 67, column 4 lines 1 – 10);

means for communicating the monitored parameters with an IMD (Figure 28, column 3 lines 9 – 67, column 4 lines 1 – 10, column 8 lines 40 – 57);

means for processing the monitored parameters (Figure 28, column 3 lines 9 – 67, column 4 lines 1 – 10, column 8 lines 40 – 57);

means for controlling the drug delivery device based on the processing of the sensed parameters (Figure 28, column 3 lines 9 – 67, column 4 lines 1 – 10, column 8 lines 40 – 57).

4. The system of claim 3, further comprising:

means for sensing physiological parameters through the IMD (Figure 28, column 3 lines 9 – 67, column 4 lines 1 – 10);

means for processing the sensed physiological parameters relative to a drug delivered by the drug delivery system (Figure 28, column 3 lines 9 – 67, column 4 lines 1 – 10); and

means for controlling the drug delivery system in response to the processing of the sensed physiological parameters (Figure 28, column 3 lines 9 – 67, column 4 lines 1 – 10).

5. The system of claim 3, further comprising means for controlling a therapy delivered by the IMD based upon the means for processing the monitored parameters (Figure 28, column 3 lines 9 – 67, column 4 lines 1 – 10).

6. An implantable medical device comprising:

a microprocessor for controlling cardiac therapy parameters (Figure 28, column 3 lines 9 – 67, column 4 lines 1 – 10);

a lead for delivering electrical stimulation to cardiac tissue and monitoring physiologic parameters of the tissue (Figure 28, column 3 lines 9 – 67, column 4 lines 1 – 10); and

a telemetry unit for receiving the parameters from the lead and information from a drug delivery device, the information identifying whether an expected drug therapy is delivered, wherein the microprocessor varies the cardiac therapy delivery through the lead based upon parameters and the information (Figure 28, column 3 lines 9 – 67, column 4 lines 1 – 10, column 8 lines 40 – 57).

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

The Applicant contends that Ellinwood, Jr. Fails to disclose monitoring the parameters of a drug delivery device. The Examiner disagrees.

The Examiner has added additional citations within the Ellinwood, Jr. to clarify his rejection and application of the art (see above). Ellinwood, Jr. discloses controlling a drug delivery device comprising a dispensing mechanism, and a dispenser control mechanism. The reference further teaches circuitry to control the dispensing mechanism to prevent medication overdoses. Therefore, the parameters of the device are in fact monitored and the device is controlled based on monitored parameters. The applied prior art is sufficient to reject the claims as currently presented.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kai Rajan whose telephone number is (571)272-3077. The examiner can normally be reached on Monday - Friday 9:00AM to 4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson can be reached on 571-272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kai Rajan/
Examiner, Art Unit 3769

/Michael C. Astorino/
Primary Examiner, Art Unit 3769

August 3, 2009